SECTION 6
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Ashley Pyle
Regulatory Affairs Manager
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Secondary Contact: Jennifer Kimball
Director of Regulatory Affairs
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Date Prepared: December 20, 2013

2. Proposed Device:

Trade Name: Injection Gold Probe™ Bipolar Electrohemostasis Catheter
Classification Name: Unit, Electrosurgical, Endoscopic (with accessories)
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

3. Predicate Device:

Trade Name: Injection Gold Probe™ Bipolar Electrohemostasis Catheter
Manufacturer and Clearance Number: Boston Scientific Corporation, K110887
Classification Name: Unit, Electrosurgical, Endoscopic (with accessories)
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

4. Proposed Device Description:

The Injection Gold Probe Catheter is an injection therapy and bipolar electrohemostasis catheter with irrigation capabilities. The Injection Gold Probe Catheter is available in a working length of 210 cm with outer diameters of 7F (2.3 mm) and 10F (3.3 mm), compatible with a minimum of 2.8 mm and 3.7 mm scope channels, respectively. The catheter shaft provides firmness for perpendicular and tangential use, while the Mediglide coating on the catheter promotes minimal friction during endoscope passage.

I. Injection Therapy

Each Injection Gold Probe Catheter contains a 25 gauge injection needle for injection therapy. The catheter handle contains the injection needle hub. Injection is performed by attaching a luerlock syringe to the "Injection" hub and advancing the needle.

II. Bipolar Electrohemostasis

The gold-spiral electrode on the probe tip provides bipolar electrohemostasis. The Injection Gold Probe Catheter connects directly to the Endostat™ family of Bipolar Electrosurgical Generators. Or utilize the Bipolar Cable Adapter supplied by Boston Scientific for other bipolar electrosurgical generators.

III. Irrigation

Irrigation with saline or sterile water is performed by connecting the irrigation hub to the irrigation port of the bipolar generator or to a 30 cm^3 (30 cc) or 60 cm^3 (60 cc) luer-lock syringe or mechanical irrigation system for generators without irrigation capability.

5. Intended Use/Indications for Use:
The Injection Gold Probe™ Bipolar Electrohemostasis Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following:

- Peptic Ulcers
- Dieulafoy Lesions
- Mallory-Weiss Tears
- Bleeding Polyp Stalks
- Arteriovenous Malformations (AVMs)
- Angiomata

The Injection Gold Probe Bipolar Electrohemostasis Catheter also has irrigation capability. Any other use is not recommended.

6. Description of Change for this Submission:
The following changes are being made to the proposed Injection Gold Probe Bipolar Electrohemostasis Catheter:

- The current PTFE coating on the Injection Gold Probe (IGP) Needle Hub to Hypotube Assemblies, is changing to a slightly modified PTFE coating.
- The current chemical weld used to attach the hypotube to injection hub, is being replaced with an adhesive bond.

7. Technological Characteristics:
The proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter has the same fundamental design, operating principal and intended use as the predicate Injection Gold Probe™ Bipolar Electrohemostasis Catheter (K110887). The proposed device has material differences when compared to the currently marketed Injection Gold Probe™ Bipolar Electrohemostasis Catheter (K110887).

8. Performance Data:
Biocompatibility Testing has been performed to demonstrate that the material changes made to the proposed device are biocompatible.

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Bench Testing has been performed on the proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter to demonstrate that the modified device meets the required specifications of the completed tests. The following bench tests were performed:

- Combination Therapy Device
- Device Irrigation Flow Rate
- Injection Needle Flow Rate
- Injection Needle Extension and Retraction
- Injection Needle Retraction Lock
- Injection Hub to 22-gauge Hypotube Joint Tensile Strength
- 25-gauge Injection Needle to the 22-Gauge Hypotube Joint Tensile Strength
- Needle Specification

9. Conclusion:
All biocompatibility tests conducted on the proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter passed. Therefore, the Injection Gold Probe™ Bipolar Electrohemostasis Catheter is considered biocompatible.

All device bench tests results were acceptable. The data demonstrate that the Injection Gold Probe™ Bipolar Electrohemostasis Catheter meets design specifications and is suitable for its intended use.

Boston Scientific Corporation has demonstrated that the proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter is substantially equivalent to Boston Scientific Corporation's currently marketed Injection Gold Probe™ Bipolar Electrohemostasis (K110887).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2014

Boston Scientific Corporation
Ashley Santos
Regulatory Affairs Manager
100 Boston Scientific Way
Marlborough, MA 01752

Re: K133933
Trade/Device Name: Injection Gold Probe™ Bipolar Electrohemostasis Catheter
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: February 28, 2014
Received: March 4, 2014

Dear Ashley Santos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	To Be Determined K133933
Device Name:	Injection Gold Probe™ Bipolar Electrohemostasis Catheter
Indications For Use:	The Injection Gold Probe™ Bipolar Electrohemostasis Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following: • Peptic Ulcers • Dieulafoy Lesions • Mallory-Weiss Tears • Bleeding Polyp Stalks • Arteriovenous Malformations (AVMs) • Angiomata The Injection Gold Probe Bipolar Electrohemostasis Catheter also has irrigation capability. Any other use is not recommended.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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